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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,533	09/05/2000	Dominique P. Bridon	REDC-1510USA	3921

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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/25/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,533

Applicant(s)

BRIDON ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003 and 16 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,19-21 and 31-58 is/are pending in the application.
- 4a) Of the above claim(s) 32-35,40-51,54 and 56-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6, 19-21, 31, 36-39, 52, 53, and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of receipt and entry of the amendments submitted 24 February and 16 June, 2003, wherein claims 2, 5, 7-18 and 22-30 were canceled without prejudice or disclaimer, claims 1, 3, 4, 6, 19, 20, and 21 amended, and new claims 31-58 submitted. Newly submitted claims 32-35, 40-51, and 54 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the product claims are directed toward conjugated peptides with different structural features and attendant biochemical activities. The submitted methodology claims are directed toward a method of use for the claimed peptides. The peptides are independent and distinct from the claimed invention since they can be employed in a number of materially different processes such as diagnostic or immunological methodologies. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-35, 40-51, and 54 are withdrawn from further consideration as being directed towards a nonelected invention (refer to 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03). Claims 1, 3, 4, 6, 19-21, 31, 36-39, 52, 53, and 55 are currently under consideration.

35 U.S.C. § 112, Second Paragraph

2. Claims 19-21, 31, 36-39, 53, and 55 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are directed toward a "composition" for the use in the prevention and treatment of HIV infection. However, the only component listed in the claims

is a modified antiviral peptide. The term composition has an art-recognized meaning and refers to a mixture of various elements or ingredients. Accordingly, it is not readily manifest which other components comprise the claimed composition (i.e., pharmaceutical
5 buffer, preservative, etc.). Appropriate correction is required.

35 U.S.C. § 112, First Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most
15 nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3, 4, 6, 19-21, 31, 36-39, 52, 53, and 55 are rejected under 35 U.S.C. § 112, first paragraph, because the specification
20 does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims are broadly directed toward modified antiviral peptides "comprising" the indicated SEQ ID NOS. Appropriately drafted claim
25 language directed toward the specific peptides (e.g., an isolated and purified chemically modified anti-viral peptide consisting of a DP-178 peptide that has been modified to contain a succinimidyl or maleimido group at the __, wherein said peptide displays a reduced susceptibility to protease degradation as compared to the
30 unmodified DP-178 peptide ... and said peptide is consists of an amino acid sequence selected from the group consisting of ...). Absent appropriate amendment to the claim language, the claims are currently rejected as set forth below.

35 The first paragraph of 35 U.S.C. § 112 requires that the scope of the claims must bear a reasonable correlation to the scope of

enablement provided by the specification (refer to M.P.E.P. §§ 706.03(n) and 796.03(z)). *In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (C.C.P.A. 1970). *In re Vaeck*, 20 U.S.P.Q.2d 1438 (C.A.F.C. 1991). Particularly where the subject matter is directed
5 towards arts where the results are unpredictable. *In re Sol*, 1938 CD 723; 497 O.G. 546. This is because in arts such as chemistry it is not obvious from the disclosure of one species, what other species will work. *In re Dreshfield* 1940 CD 351; 518 O.G. 255.

The only requirement for the claimed invention is that a
10 particular core sequence must be present in the modified peptide. Thus the claims allow for polypeptides with significant additions at either or both termini. However, it has been well-documented in the art that the addition of flanking sequences can have an unpredictable influence on the biochemical properties of any given
15 peptide. The invention is predicated upon the inhibition of an active fusion conformation that is generated during virion-cell surface receptor binding and entry. Thus, the peptide of interest needs to be able to interact with the complex in a highly specific manner in order to effectively inhibit viral replication. However,
20 it seems extremely unlikely that a full-length modified viral peptide would display the same specificity and antiviral activity. The skilled artisan would reasonably expect steric hindrance to prevent the polypeptide of interest from binding to the complex. Moreover, the disclosure fails to provide sufficient guidance
25 pertaining to those additional flanking sequences that can be included without abrogating antiviral activity. Accordingly, when all the aforementioned factors are considered in toto, it would clearly required undue experimentation from the skilled artisan to practice the claimed invention.

Correspondence

5. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers

must conform with the notice published in the Official Gazette,
1096 OG 30 (November 15, 1989). Official communications should be
directed toward the following Group 1600 fax number: (703) 872-
9306. Any inquiry concerning this communication should be directed
5 to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-
2227. The examiner can normally be reached Monday through Thursday
from 8:30 AM to 6:00 PM. A message may be left on the examiner's
voice mail service. If attempts to reach the examiner are
unsuccessful, the examiner's supervisors, Laurie Scheiner or James
10 Housel, can be reached at (703) 308-1122 or (703) 308-4027,
respectively. Any inquiry of a general nature or relating to the
status of this application should be directed to the Group 1600
receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

20 September, 2003